

FILED

JUL 14 2011

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF COLUMBIA

Mark, U.S. District & Bankruptcy
Courts for the District of Columbia

Brian S. Hooker, Ph.D., P.E.)
2211 College View Drive,)
Redding, CA 96003)
Plaintiff,)

v.)

Kathleen Sebelius as SECRETARY,)
U. S. DEPARTMENT OF HEALTH)
AND HUMAN SERVICES (DHHS))
200 Independence Avenue, S.W. -)
Washington, D.C. 20201-0004)

and)
Thomas R. Frieden, MD, MPH as)
Director, THE CENTERS FOR)
DISEASE CONTROL AND)
PREVENTION (CDC))
1600 Clifton Rd)
Atlanta, GA 30333,)
a component agency of defendant HHS,)

Defendants.)

Case: 1:11-cv-01276

Assigned To : Jackson, Amy Berman

Assign. Date : 7/14/2011

Description: FOIA/Privacy Act

COMPLAINT FOR INJUNCTIVE RELIEF

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552, for injunctive and other appropriate relief for the disclosure and release of agency records improperly withheld from plaintiff by the Centers for Disease Control and Prevention, a component agency of defendant DHHS.

JURISDICTION AND VENUE

2. This court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B). This court also has

jurisdiction over this action pursuant to 28 U.S.C. § 1331. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B).

THE PARTIES

3. Plaintiff Dr. Brian S. Hooker is a private citizen, residing at 2211 College View Drive, Redding, CA 96003.

4. Defendant Department of Health and Human Services ("DHHS") is a Department of the Executive Branch of the United States government. DHHS is an "agency" within the meaning of 5 U.S.C. § 552(f), comprised of component agencies, including the Centers for Disease Control and Prevention.

5. The Centers for Disease Control and Prevention ("CDC") is a component agency of defendant DHHS. CDC is an "agency" within the meaning of 5 U.S.C. § 552(f).

PLAINTIFF'S FOIA REQUEST AND CDC'S RESPONSE

COUNT ONE

6. By email to CDC dated March 11, 2005, plaintiff requested, inter alia, copies of "written correspondences both between ALL CDC employees and between ALL CDC employees and ALL outside persons regarding the thimerosal and autism study completed using the Danish Psychiatric Central Research Register by Kreesten Madsen (From the Danish Epidemiology Science Centre, Department of Epidemiology and Social Medicine, University of Aarhus, Denmark) as reported in the publication: "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data," Madsen et al. 2003 Pediatrics 112:604-606."

7. By letter to plaintiff on April 6, 2005, CDC sent an invoice for \$1394.00 to be remitted for charges associated with records search for the National Center for Birth Defects and Developmental Disabilities and the Office of the Executive Secretary. The plaintiff subsequently remitted \$1394.00 to continue to the FOIA process.

8. By letter to plaintiff on June 24, 2005, CDC provided copies of 7 communications between the CDC and private citizens concerning the content of thimerosal (a mercury-based preservative) in infant vaccines. In its response letter to plaintiff, CDC indicated that the "program staff are still processing your request." In addition, the CDC stated that "We are withholding predecisional internal communications because release would interfere with the agency's deliberative process. This decision is based on the Act at 5 U.S.C. § 522(b)(5) and the Department's implementing regulation at 45 C.F.R. § 5.66(a)." CDC provided no indication of whether additional documents responsive to plaintiff's request had been located and withheld.

9. By email to the CDC dated August 28, 2005, plaintiff inquired to the status of the original FOIA request.

10. By letter to the plaintiff on September 1, 2005, CDC stated "You asked specifically about records from the National Immunization Program. That program did not find responsive records on this request." CDC also stated "The National Center on Birth Defects and Developmental Disabilities has not yet completed processing this request."

11. After several months with no reply from CDC, by email, plaintiff appealed the response (actual date of email correspondence unknown) to the Department of Health and Human Services FOIA Appeals Office. The plaintiff questioned the lack of records

uncovered by the CDC National Immunization Program and the lack of timely response by the National Center for Birth Defects and Developmental Disabilities.

12. By letter dated September 8, 2006, DHHS FOIA appeals office released inter alia email correspondences between Danish researchers responsible for the paper "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data," Madsen et al. 2003 Pediatrics 112:604-606 and Dr. Diana Schendel of CDC. The letter stated that the documents "were located by the CDC National Center on Birth Defects and Developmental Disabilities." All correspondences were heavily redacted with no apparent explanation or reference to FOIA exemptions. A subsequent letter dated October 6, 2006 by the DHHS FOIA appeals office indicated that the CDC had satisfied the full scope of the search. The letter also indicated that plaintiff had exhausted all applicable administrative remedies with respect to its FOIA appeal to the DHHS.

CAUSE OF ACTION FOR COUNT ONE

Violation of the Freedom of Information Act for Wrongful Withholding of Agency Records

13. Defendants have wrongfully withheld agency records requested by plaintiff. Defendants have wrongfully extended 5 U.S.C. § 552(a)(4)(B) exemption 5 to parties outside of CDC by redacting email replies from researchers not employed by CDC and not acting as "consultants" (*Klamath Water Users Protective Ass'n v. Department of the Interior*, 189 F.3d 1034, 1038 (9th Cir. 1999), *aff'd*, 532 U.S. 1 (2001)).

14. Defendants have not conducted an adequate search as no records were released from the CDC's National Immunization Program. Later FOIA requests to the

CDC yielded significant numbers of correspondences between Dr. Diane Simpson, then acting Deputy Director of the National Immunization Program, and Dr. Kreesten Madsen, the paper's primary author (documents will be submitted as an exhibit). Thus, it is apparent that the CDC did not thoroughly search National Immunization Program records for this particular FOIA request.

15. Plaintiff asks that any application of the (b)(5) exception in this case be waived upon the judge's discretion based on the important and timely nature of the connection of thimerosal in vaccines to neurodevelopmental disorders including autism. Although the CDC consistently denies a causal relationship between thimerosal and autism, there is a mounting body of compelling scientific literature that supports this relationship including:

- Olczak M, et al.. Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats. *Behavioural Brain Research* (2010), doi:10.1016/j.bbr.2011.04.026,
- Hewitson L, et al. Delayed Acquisition of Neonatal Reflexes in Newborn Primates Receiving a Thimerosal-Containing Hepatitis B Vaccine: Influence of Gestational Age and Birth Weight. *J. Toxicology and Environmental Health, Part A* 2010; 73: 1298-1313,
- Dorea JG. Integrating Experimental (In Vitro and In Vivo) Neurotoxicity Studies of Low-Dose Thimerosal Relevant to Vaccines. *Neurochem Res.* 2011 Jun; 36(6): 927-38. [Epub 2011 Feb 25],

- Olczak M, et al. Lasting Neuropathological Changes in Rat Brain After Intermittent Neonatal Administration of Thimerosal. *Folia Neuropathologica* 2010; 48(4): 258-269,
- Geier DA, et al. Blood Mercury Levels in Autism Spectrum Disorder: Is There a Threshold Level? *Acta Neurobiology Experimentalis (Warsaw)* 2010; 70: 177-186,
- Elsheshtawy E, et al. Study of Some Biomarkers in Hair of Children with Autism. *Middle East Current Psychiatry* 2011; 18: 6-10,
- Kern JK, et al. A Biomarker of Mercury Body-Burden Correlated with Diagnostic Domain Specific Clinical Symptoms of Autism Spectrum Disorder. *Biometals* 2010; 23: 1043-1051,
- Majewska MD, et al. Age-Dependent Lower or Higher Levels of Hair Mercury in Autistic Children than in Health Controls. *Acta Neurobiology Experimentalis (Warsaw)* 2010; 70: 196-208,
- Minami T, et al. Induction of Metallothionein in Mouse Cerebellum and Cerebrum with Low-Dose Thimerosal Injection. *Cell Biology and Toxicology* 2010; 26: 143-152,
- Olczak M, et al. Neonatal Administration of Thimerosal Causes Persistent Changes in Mu Opioid Receptors in the Rat Brain. *Neurochemical Research* 2010; 35: 1840-1847,
- Ratajczak H. Theoretical Aspects of Autism: Causes - A Review. *J. Immunotoxicology* 2011; 8: 68-79,

- Hewitson L, et al. Influence of Pediatric Vaccines on Amygdala Growth and Opioid Ligand Binding in Rhesus Macaque Infants: A Pilot Study. Acta Neurobiology Experimentalis (Warsaw) 2010; 70: 147-164,
- Lakshmi Priya MD, et al. Level of Trace Elements (Copper, Zinc, Magnesium and Selenium) and Toxic Elements (Lead and Mercury) in the Hair and Nail of Children with Autism. Biological Trace Element Research 2010 Jul 13 [Epub ahead of print], and
- Wyrembek P, et al, "Intermingled Modulatory Neurotoxic Effects of Thimerosal and Mercuric Ions on Electrophysiological Responses to GABA and NMDA in Hippocampal Neurons" Journal of Physiology and Pharmacology 2010; 61: 753-758.

16. Plaintiff has exhausted the applicable administrative remedies with respect to defendants' wrongful withholding of the requested records.

17. Plaintiff is entitled to injunctive relief with respect to the release and disclosure of the requested documents.

PLAINTIFF'S FOIA REQUEST AND CDC'S RESPONSE

COUNT TWO

18. By email to CDC dated April 20, 2005, plaintiff requested, inter alia, copies of written correspondences between Dr. Sarah Parker and Dr. James Todd of the University of Colorado Health Sciences Center and all CDC employees in the National Immunization Program. The request was also for all documents pertinent to the publication "Thimerosal-containing vaccines and autistic spectrum disorder: a critical

review of published original data" that appeared in the journal Pediatrics in 2005, that was coauthored by CDC scientists Dr. Larry Pickering and Dr. Ben Schwartz.

19. By letter to plaintiff on September 9, 2005, CDC found five "deliberative" documents that they refused to release. Specifically they stated, "We are withholding these records because release of this predecisional internal material would interfere with the agency's deliberative process based upon the Act at 5 U. S. C. 522 (b)(5) and the Department's implementing regulation of 45 C.F.R. § 5.66(a)."

20. By email, plaintiff on October 5, 2005 appealed the response to the Department of Health and Human Services FOIA Appeals Office. The plaintiff questioned the validity of the (b)(5) predecisional exception used to withhold the found documents. The plaintiff also questioned the paucity of material uncovered given the role of the two CDC scientists as co-authors on the publication.

21. By letter dated November 4, 2010, DHHS FOIA appeals office released seven additional documents based on the improper application of the (b)(5) exception and the Office of Management and Budget (OMB) circular 110, revision 99, section 36. However, the documents released were not adequate, based on the OMB circular 110, rev. 99 section 36, which states that documents must be released sufficient to repeat the analysis to obtain results on a publication that has the force and effect of law.

CAUSE OF ACTION FOR COUNT TWO

Violation of the Freedom of Information Act for Wrongful Withholding of
Agency Records

22. Defendants have not provided adequate documents for applying the OMB circular 110, rev. 99, section 36 which states that documents must be released sufficient to repeat the analysis that led to the results of the publication, for a publication that has the force and effect of law. The publication in question, "Thimerosal-containing vaccines and autistic spectrum disorder: a critical review of published original data" by Parker et al. has been used by the CDC to justify the continued use of thimerosal containing vaccines.

23. Plaintiff asks that any application of the (b)(5) exception in this case be waived upon the judge's discretion based on the important and timely nature of the connection of thimerosal in vaccines to neurodevelopmental disorders including autism. Although the CDC consistently denies a causal relationship between thimerosal and autism, there is a mounting body of compelling scientific literature that supports this relationship including:

- Olczak M, et al.. Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats. Behavioural Brain Research (2010), doi:10.1016/j.bbr.2011.04.026,
- Hewitson L, et al. Delayed Acquisition of Neonatal Reflexes in Newborn Primates Receiving a Thimerosal-Containing Hepatitis B Vaccine: Influence of Gestational Age and Birth Weight. J. Toxicology and Environmental Health, Part A 2010; 73: 1298-1313,

- Dorea JG. Integrating Experimental (In Vitro and In Vivo) Neurotoxicity Studies of Low-Dose Thimerosal Relevant to Vaccines. *Neurochem Res.* 2011 Jun; 36(6): 927-38. [Epub 2011 Feb 25],
- Olczak M, et al. Lasting Neuropathological Changes in Rat Brain After Intermittent Neonatal Administration of Thimerosal. *Folia Neuropathologica* 2010; 48(4): 258-269,
- Geier DA, et al. Blood Mercury Levels in Autism Spectrum Disorder: Is There a Threshold Level? *Acta Neurobiology Experimentalis (Warsaw)* 2010; 70: 177-186,
- Elsheshtawy E, et al. Study of Some Biomarkers in Hair of Children with Autism. *Middle East Current Psychiatry* 2011; 18: 6-10,
- Kern JK, et al. A Biomarker of Mercury Body-Burden Correlated with Diagnostic Domain Specific Clinical Symptoms of Autism Spectrum Disorder. *Biometals* 2010; 23: 1043-1051,
- Majewska MD, et al. Age-Dependent Lower or Higher Levels of Hair Mercury in Autistic Children than in Health Controls. *Acta Neurobiology Experimentalis (Warsaw)* 2010; 70: 196-208,
- Minami T, et al. Induction of Metallothionein in Mouse Cerebellum and Cerebrum with Low-Dose Thimerosal Injection. *Cell Biology and Toxicology* 2010; 26: 143-152,
- Olczak M, et al. Neonatal Administration of Thimerosal Causes Persistent Changes in Mu Opioid Receptors in the Rat Brain. *Neurochemical Research* 2010; 35: 1840-1847,

- Ratajczak H. Theoretical Aspects of Autism: Causes - A Review. J. Immunotoxicology 2011; 8: 68-79,
- Hewitson L, et al. Influence of Pediatric Vaccines on Amygdala Growth and Opioid Ligand Binding in Rhesus Macaque Infants: A Pilot Study. Acta Neurobiology Experimentalis (Warsaw) 2010; 70: 147-164,
- Lakshmi Priya MD, et al. Level of Trace Elements (Copper, Zinc, Magnesium and Selenium) and Toxic Elements (Lead and Mercury) in the Hair and Nail of Children with Autism. Biological Trace Element Research 2010 Jul 13 [Epub ahead of print], and
- Wyrembek P, et al, "Intermingled Modulatory Neurotoxic Effects of Thimerosal and Mercuric Ions on Electrophysiological Responses to GABA and NMDA in Hippocampal Neurons" Journal of Physiology and Pharmacology 2010; 61: 753-758.

24. Plaintiff has exhausted the applicable administrative remedies with respect to defendants' wrongful withholding of the requested records.

25. Plaintiff is entitled to injunctive relief with respect to the release and disclosure of the requested documents.

PLAINTIFF'S FOIA REQUEST AND CDC'S RESPONSE

COUNT THREE

26. By email to CDC dated April 23, 2005, plaintiff requested, inter alia, copies of written correspondences between Dr. Thomas Verstraeten and all CDC employees in the National Immunization Program and the Office of the Director after Dr. Verstraeten had terminated employment with the CDC.

27. By letter to plaintiff on September 9, 2005, CDC provided copies of various correspondences between CDC employees and Dr. Verstraeten, but omitted any documents referencing the study "Safety of thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases" by Verstraeten et al. 2003 that appeared in the journal Pediatrics. In its response letter to plaintiff, CDC indicated that "We are withholding a draft manuscript and other predecisional documents. Release of this type of material would interfere with the agency's deliberative process based upon the Act at 5 U. S. C. § 522 (b)(5) and the Department's implementing regulation of 45 C.F.R. § 5.66(a)."

28. By email, plaintiff on October 5, 2005 appealed the response to the Department of Health and Human Services FOIA Appeals Office. The plaintiff questioned the thoroughness of the search given the paucity of material uncovered by the search especially in light of an original invoice provided by the CDC that indicated that there were approximately 1760 pages of material. The plaintiff also questioned the validity of the (b)(5) predecisional exception used to withhold over 300 pages of information.

29. By letter dated November 4, 2010, DHHS FOIA appeals office released two additional documents for a total of two pages based on the improper application of the (b)(2) exception. The DHHS FOIA appeals office reiterated the original CDC letter (September 9, 2005), upholding the (b)(5) exception, stating, "In this case, Dr. Verstraeten provided his expertise in a consultative nature to the CDC after his employment with that agency ended. The withheld information includes emails discussing the draft manuscript."

CAUSE OF ACTION FOR COUNT THREE

Violation of the Freedom of Information Act for Wrongful Withholding of
Agency Records

30. Defendants have not provided adequate justification for applying the (b)(5) "predecisional" exception to over 300 pages of documents. This standard appears to be applied only to documents pertinent to a single publication, pertaining to thimerosal in vaccines and its causal relationship to neurodevelopmental disorders including autism.

31. Plaintiff asks that any application of the (b)(5) exception in this case be waived upon the judge's discretion based on the important and timely nature of the connection of thimerosal in vaccines to neurodevelopmental disorders including autism. Although the CDC consistently denies a causal relationship between thimerosal and autism, there is a mounting body of compelling scientific literature that supports this relationship including:

- Olczak M, et al.. Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats. Behavioural Brain Research (2010), doi:10.1016/j.bbr.2011.04.026,
- Hewitson L, et al. Delayed Acquisition of Neonatal Reflexes in Newborn Primates Receiving a Thimerosal-Containing Hepatitis B Vaccine: Influence of Gestational Age and Birth Weight. J. Toxicology and Environmental Health, Part A 2010; 73: 1298-1313,

- Dorea JG. Integrating Experimental (In Vitro and In Vivo) Neurotoxicity Studies of Low-Dose Thimerosal Relevant to Vaccines. *Neurochem Res.* 2011 Jun; 36(6): 927-38. [Epub 2011 Feb 25],
- Olczak M, et al. Lasting Neuropathological Changes in Rat Brain After Intermittent Neonatal Administration of Thimerosal. *Folia Neuropathologica* 2010; 48(4): 258-269,
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- Ratajezak H. Theoretical Aspects of Autism: Causes - A Review. J. Immunotoxicology 2011; 8: 68-79,
- Hewitson L, et al. Influence of Pediatric Vaccines on Amygdala Growth and Opioid Ligand Binding in Rhesus Macaque Infants: A Pilot Study. Acta Neurobiology Experimentalis (Warsaw) 2010; 70: 147-164,
- Lakshmi Priya MD, et al. Level of Trace Elements (Copper, Zinc, Magnesium and Selenium) and Toxic Elements (Lead and Mercury) in the Hair and Nail of Children with Autism. Biological Trace Element Research 2010 Jul 13 [Epub ahead of print], and
- Wyrembek P, et al, "Intermingled Modulatory Neurotoxic Effects of Thimerosal and Mercuric Ions on Electrophysiological Responses to GABA and NMDA in Hippocampal Neurons" Journal of Physiology and Pharmacology 2010; 61: 753-758.

32. Plaintiff has exhausted the applicable administrative remedies with respect to defendants' wrongful withholding of the requested records.

33. Plaintiff is entitled to injunctive relief with respect to the release and disclosure of the requested documents.

PLAINTIFF'S FOIA REQUEST AND CDC'S RESPONSE

COUNT FOUR

34. By email to CDC dated December 14, 2004, plaintiff requested, inter alia, copies of written correspondences between ALL CDC employees and between ALL CDC employees and Nick Andrews and Elizabeth Miller (UK-GPRD) regarding their

presentation at the Institute of Medicine Vaccine Safety Review Committee Meeting on Feb. 9, 2004.

35. By email to CDC dated December 29, 2004, plaintiff requested that the FOIA request outlined in the December 14, 2004 be extended to include all written correspondences to and from Dr. Brent Taylor (UK-GPRD).

36. By letter to plaintiff on January 31, 2005, CDC provided copies of email correspondences among Dr. Elizabeth Miller, Dr. Robert Chen and Dr. Thomas Verstraeten between June 26, 2001 and November 8, 2001. In its response letter to plaintiff, CDC indicated that "Please note that Dr. Chen did not retain any of his replies to the enclosed E-mails". CDC provided no indication of whether additional documents responsive to plaintiff's request had been located and withheld. Significant and critical time gaps were noted in the correspondences, especially between June 27, 2001 and August 10, 2001. Released records suggest that additional correspondences were made during that time period.

37. By email, plaintiff on February 23, 2005 appealed the response to the Department of Health and Human Services FOIA Appeals Office. The plaintiff questioned the thoroughness of the search given the paucity of material uncovered by the search and that email replies by Dr. Chen were not obtained.

38. By letter dated July 19, 2005, DHHS FOIA appeals office reiterated the original CDC letter (January 31, 2005) stating, "CDC searched the files of the NIP and no records of the e-mails were located. Further, Dr. Chen was specifically asked to search his files and he reiterated that he did not retain copies of the e-mails he sent."

CAUSE OF ACTION FOR COUNT FOUR

Violation of the Freedom of Information Act for Wrongful Withholding of
Agency Records

39. Defendants have not completed a thorough search for agency records requested by plaintiff, including especially the email replies by Dr. Robert Chen.

40. Defendants have not searched for records within the time period June 27, 2001 and August 10, 2001.

41. Plaintiff asks that any application of the (b)(5) exception in this case be waived upon the judge's discretion based on the important and timely nature of the connection of thimerosal in vaccines to neurodevelopmental disorders including autism. Although the CDC consistently denies a causal relationship between thimerosal and autism, there is a mounting body of compelling scientific literature that supports this relationship including:

- Olczak M, et al.. Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats. Behavioural Brain Research (2010), doi:10.1016/j.bbr.2011.04.026,
- Hewitson L, et al. Delayed Acquisition of Neonatal Reflexes in Newborn Primates Receiving a Thimerosal-Containing Hepatitis B Vaccine: Influence of Gestational Age and Birth Weight. J. Toxicology and Environmental Health, Part A 2010; 73: 1298-1313,

- Dorea JG. Integrating Experimental (In Vitro and In Vivo) Neurotoxicity Studies of Low-Dose Thimerosal Relevant to Vaccines. *Neurochem Res.* 2011 Jun; 36(6): 927-38. [Epub 2011 Feb 25],
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- Geier DA, et al. Blood Mercury Levels in Autism Spectrum Disorder: Is There a Threshold Level? *Acta Neurobiology Experimentalis (Warsaw)* 2010; 70: 177-186,
- Elsheshtawy E, et al. Study of Some Biomarkers in Hair of Children with Autism. *Middle East Current Psychiatry* 2011; 18: 6-10,
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42. Plaintiff has exhausted the applicable administrative remedies with respect to defendants' wrongful withholding of the requested records.

43. Plaintiff is entitled to injunctive relief with respect to the release and disclosure of the requested documents.

REQUESTED RELIEF

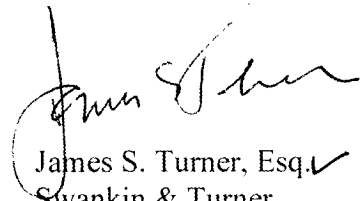
WHEREFORE, plaintiff prays that this Court:

- A. Order defendants to disclose the requested records in their entireties and make copies available to plaintiff;
- B. Provide for expeditious proceedings in this action;
- C. Award plaintiff its costs and reasonable attorneys fees incurred in this action;

And

D. Grant such other relief as the Court may deem just and proper.

Respectfully submitted,



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